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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STAN CIPKOWSKI

Appeal 2011-007578
Application 08/981,665
Technology Center 1600

Before DONALD E. ADAMS, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 16, 18, and 19. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claim 16 is the only independent claim on appeal, and reads as follows:

16. A drug of abuse immunoassay test card for testing a liquid test specimen in a container having an open top and comprising a thin flat member having a rectangular outline and having front and rear surfaces, said thin flat member having a longitudinal dimension extending between top and bottom ends defining a length and having a width less than said length, and being shaped to be insertable longitudinally into a container to contact a liquid test specimen therein,

one or more immunoassay test strips each having thereon immunoassay means to visually indicate presence or absence of a selected drug of abuse disposed longitudinally side-by-side in parallel within said thin flat member and enclosed between said front and rear surfaces,

each said one or more test strips having a bottom end defining a sample contacting portion and further having a test portion spaced longitudinally therefrom wherein, in use, the liquid test specimen moves by capillary action from the sample contacting portion to the test portion at which the presence or absence of the selected drug of abuse in the fluid sample is visually indicated,

the bottom end of each said one or more test strips being disposed at the bottom end of said thin flat member but spaced from the bottom end of said thin flat member, the top end of each said one or more test strips being spaced from the top end of said thin flat member,

said front surface of said thin flat member having a plurality of openings therein to register with and expose each of the sample contacting and test portions on the exposed surface of each of said one or more test strips exposed by said openings, including a sample contacting opening over said sample contacting portion of the test strip and a test opening over said test portion of said test strip,

said openings located so that the liquid test specimen initially travels through said sample contacting opening and contacts the exposed surface of the sample contacting portions of each of said one or more test strips exposed beneath said sample contacting openings and then moves by capillary action from the sample contacting portion of said one or more test strips to the test portion of said one or more test strips,

further comprising means within said thin flat member between said front and rear surfaces for defining one or more longitudinally extending slots to longitudinally dispose said one or more test strips, each said one or more slots having both ends closed and spaced from the respective top and bottom ends of said thin flat member, and said one or more immunoassay test strips each seated within a respective slot.

The following grounds of rejection are before us for review:

- I. Claims 16, 18, and 19 stand rejected under 35 U.S.C. § 112, first paragraph, as containing new matter.
- II. Claims 16, 18, and 19 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of May,¹ Sun,² and Boger.³ As Appellant does not argue the claims separately, we focus our analysis on claim 16, and claims 18 and 19 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

We reverse Rejection I, but affirm Rejection II.

ISSUE (New Matter)

Does the preponderance of evidence of record support the Examiner's finding that independent claim 16 contains new matter?

FINDINGS OF FACT

FF1. The Specification teaches that the “present invention relates to a test kit for the collection and testing of urine samples for drug of abuse,”

¹ May et al., WO 88/08534, published Nov. 3, 1988.

² Sun et al., US 5,238,652, issued Aug. 24, 1993.

³ Boger et al., US 4,518,565, issued May 21, 1985.

wherein the test kit comprises “a test card for indicating visually the presence of particular drugs of abuse” (Spec. 1).

FF2. Figure 9 of the instant disclosure is reproduced below:

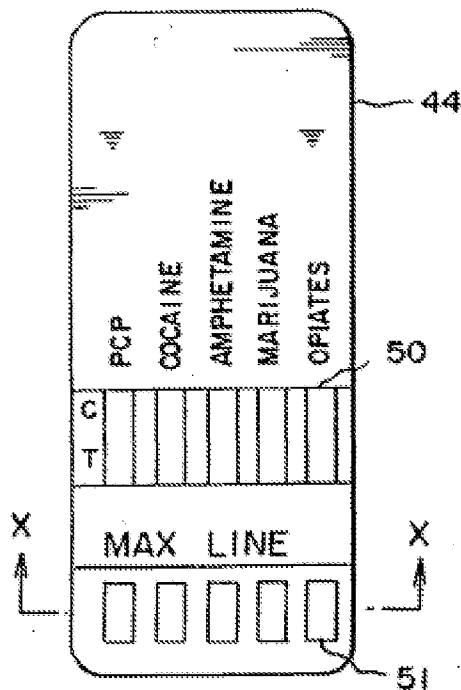


Figure 9 is a plan view of one embodiment of a test card disclosed in the Specification (*id.* at 7).

FF3. According to the Specification:

A modification of the test card is shown at 44 in Fig. 9. In this modification, the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings. The test card 44 comprises a central ply 45 [as can be seen in Figure 10, not reproduced] of styrene which has a thickness of 1.25 mm. corresponding to or slightly greater than the thickness of the test strips and slots are provided in the center ply to receive the test strips. . . . The top ply 47 is provided with a plurality of test windows 50 through which the test results as indicated by the test strips can be seen. At the lower end of the card are provided sample openings 51 through

which the liquid test specimen is able to contact the absorbent or sample portions of the test strips.

(*Id.* at 11-12.)

FF4. The Examiner finds that the disclosure, as originally filed:

does not provide support for a sample **contacting** portion **on the exposed surface** (i.e., front) **of the test strip** so that liquid sample flows through the sample opening in the thin flat member strip holder and contacts the **exposed surface** (i.e., front) of the sample portion exposed beneath (i.e., registering with) the opening.

(Ans. 4.)

FF5. Specifically, according to the Examiner:

[A]ppellant merely discloses that specimen is able to contact the “absorbent or sample portions” of the test strips through the sample openings of the card (see e.g. page 12). There is no disclosure that these portions are necessarily on, or only on, the exposed surface of the test strip.

(*Id.* at 4-5.)

ANALYSIS

Appellant argues that the claim language is not new matter, but is supported by Figure 9 and pages 11-12 on the instant Specification (App. Br. 7-8).

We conclude that Appellant has the better position.

The test for determining whether a specification is sufficient to support a particular claim “is whether the disclosure of the application relied upon ‘reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.’” *Ralston Purina Co. v. Far-*

Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983)). Thus, “[i]t is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations.” *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976) (citation omitted); *see also Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (“In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.”).

The Specification teaches that “the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings” (FF3). The Specification teaches further that at “the lower end of the card are provided sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips.” While there may be no specific disclosure that these portions are necessarily on, or only on, the exposed surface of the test strip, we conclude that the person of ordinary skill in the art would understand that Appellant reasonably had possession of a test card having a sample contacting portion on the exposed surface (i.e., front) of the test strip so that the liquid sample flows through the sample opening in the thin flat member strip holder and contacts the exposed surface (i.e., front) of the sample portion exposed beneath (i.e., registering with) the opening.

CONCLUSION OF LAW

We conclude that the preponderance of evidence of record does not support the Examiner's finding that independent claim 16 contains new matter. We thus reverse the rejection of claims 16, 18, and 19 under 35 U.S.C. § 112, first paragraph, as containing new matter.

ISSUE (Obviousness)

Does the preponderance of the evidence of record support the Examiner's conclusion that the combination of May, Sun, and Boger renders obvious the immunoassay card of claim 16?

FINDINGS OF FACT

- FF6. We adopt the Examiner's findings and conclusions as our own.
- FF7. We also highlight the following teachings of May.
- FF8. Figures 11 and 12 of May are reproduced below:

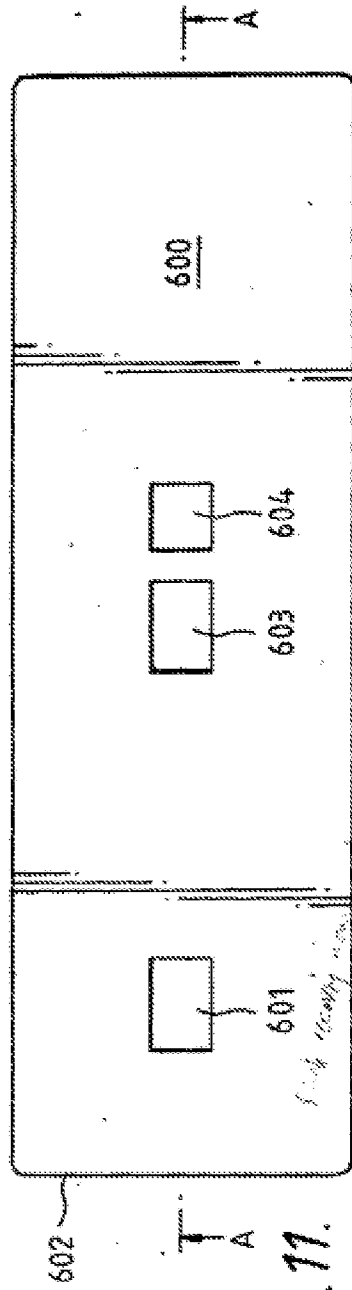


Fig. 11.

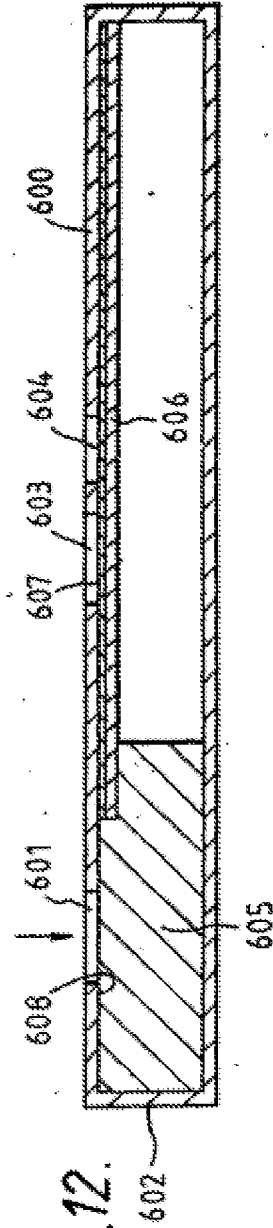


Fig. 12.

Figures 11 and 12 are drawn to the embodiment of the test strip of May: the plan view is shown in Figure 11 and the cross-sectional view is shown in Figure 12 (May p. 27).

FF9. The test strip contains an aperture 601, through which a sample may be applied (*id.* at 27-28).

FF10. As to the embodiment shown above, May teaches:

[T]he device is hollow and incorporates within it a porous sample receiving member adjacent end 602 of casing 600 and lying directly beneath aperture 601. A test strip . . . comprising a porous strip 606 backed by a transparent plastics sheet 607 is also contained within casing 600, and extends from the porous receiving member 602, with which the porous carrier is in liquid permeable contact, to the extreme other end of the casing. The transparent backing sheet 607 is in firm contact with the upper inner surface 608 of casing 600, and provides a seal against apertures 603 and 604 to prevent ingress of moisture or sample into the casing.

(*Id.* at 27.)

FF11. May teaches further:

A typical embodiment of the invention . . . an analytical test device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates *directly or indirectly* with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device also containing a labelled [sic] specific binding reagent for an analyte which labelled [sic] specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabelled [sic] specific binding reagent for the same analyte which unlabelled [sic] reagent is permanently immobilised [sic] in a detection zone on the carrier material and is therefore not mobile in the moist state, the relative positioning of the labelled [sic] reagent and detection zone being such that liquid sample applied to the

device can pick up labelled [sic] reagent and thereafter permeate into the detection zone, and the device incorporating means enabling the extent (if any) to which the labelled [sic] reagent becomes in the detection zone to be observed.

(*Id.* at 3 (emphasis added).)

ANALYSIS

Appellant argues that none of the references relied upon by the Examiner “**disclose the specific test card of the present invention**, namely one wherein the test card houses one or more immunoassay strips wherein the liquid specimen passes through the opening directly above the sample contacting portion on the front of the test strip and then proceeds via capillary action along the strip to the test portion wherein an analyte in the specimen may be visually determined through another opening in the test card” (App. Br. 12).

Specifically, Appellant asserts that “the May reference **teaches away** from the present claims because the device disclosed therein **covers up** in all cases the front surface of the test strip and **prevents** the sample from contacting the test strip on the front surface of the test strip” (*id.*; *see also* Reply Br. 9). Appellant points to Figures 11 and 12, wherein “the fluid sample is contacted only through the end of the test strip 606 which is blocked from receiving a fluid sample on the front end of the test strip” (*id.* at 12-13). Appellant further asserts that neither Sun nor Boger remedy that deficiency of May (*id.* at 13).

Appellant’s arguments have been carefully considered, but are not convincing. As can be seen from Figures 11 and 12 of May, May teaches a

test case having a test strip therein, wherein the case has an opening therein exposing a sample receiving member directly beneath the opening 601 (FF9). While in the embodiment shown in Figures 11 and 12, the sample is not directly applied to the test strip, but is instead applied to a sample receiving member, May specifically teaches that the dry porous carrier that makes up the test strip may communicate with the exterior of the casing either directly or indirectly with the exterior of the casing so that the test sample may be applied (*see* FF11; *see also* Ans. 8, 21). Thus, we agree with the Examiner (*see, e.g.,* Ans. 21) that it would have been well within the level of skill of the ordinary artisan to position a sample receiving portion of the test strip of May underneath the aperture 601 in order to apply the sample directly to the test strip.

CONCLUSION OF LAW

We conclude that the preponderance of the evidence of record supports the Examiner's conclusion that the combination of May, Sun, and Boger renders obvious the immunoassay card of claim 16. We thus affirm the rejection of claim 16 under 35 U.S.C. § 103(a) as being rendered obvious by the combination of May, Sun, and Boger. As claims 18 and 19 stand or fall with claim 16, we affirm the rejection as to those claims as well.

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TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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